



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. E. Joseph McMullen  
Associate Director, Regulatory Affairs  
Gen-Probe Incorporated  
10210 Genetic Center Drive  
San Diego, CA 92121-4362

OCT - 4 2006

Re: k061509  
Trade/Device Name: TIGRIS<sup>®</sup> DTS<sup>®</sup> GEN-PROBE<sup>®</sup> APTIMA Assay for  
*Neisseria gonorrhoeae*  
Regulation Number: 21 CFR 866.3390  
Regulation Name: *Neisseria* spp. direct serological test reagents  
Regulatory Class: Class II  
Product Code: LSL  
Dated: September 25, 2006  
Received: September 26, 2006

Dear Mr. Shea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

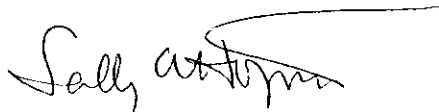
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sally A. Hojvat", with a long horizontal line extending from the end of the signature.

Sally A. Hojvat, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure



# GEN-PROBE INCORPORATED

APTIMA Assay<sup>®</sup> for *Neisseria gonorrhoeae* – Special 510(k) TIGRIS DTS

## INDICATIONS FOR USE STATEMENT

**510(k) Number:**

(if known)

**K061509**

**Device Name:**

TIGRIS<sup>®</sup> DTS<sup>®</sup> GEN-PROBE APTIMA Assay<sup>®</sup> for *Neisseria gonorrhoeae*

**Indications for**

**Use:**

The APTIMA<sup>®</sup> Assay for *Neisseria gonorrhoeae* is a target amplification nucleic acid probe test that utilizes target capture for the *in vitro* qualitative detection of ribosomal RNA (rRNA) from *Neisseria gonorrhoeae* (GC) to aid in the diagnosis of gonococcal urogenital disease using the TIGRIS<sup>®</sup> DTS<sup>®</sup> Automated Analyzer or semi-automated instrumentation as specified. The assay may be used to test the following specimens from symptomatic individuals: clinician-collected endocervical, vaginal and male urethral swab specimens; and patient-collected female and male urine specimens. The assay may be used to test the following specimens from asymptomatic individuals: clinician-collected endocervical and vaginal swab specimens; and patient-collected vaginal swab specimens<sup>1</sup> and female and male urine specimens.

<sup>1</sup>Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The vaginal swab specimen collection kit is not for home use.

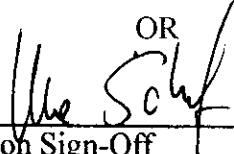
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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ☒ X  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐

  
Division Sign-Off

**Office of In Vitro Diagnostic Device  
Evaluation and Safety**

510(k) K061509